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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,874	06/07/2000	ERICH WANKER	V0179/7000	6909

7590 02/18/2004

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/463,874	Applicant(s) WANKER ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
 4a) Of the above claim(s) 7 and 12-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/31/3</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 1 and 11 have been amended as requested in the amendment of Paper filed on December 31, 2003. Claims 1-19 are pending in the instant application.

Claims 7 and 12-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Claims 1-6 and 8-11 are under examination in the instant office action.

2. Listing of claims in the amendment submitted on December 31, 2003 includes new claims 22-23, “(Status Unknown)” (page 7 of the listing). Because these claims are newly presented in the listing and there is no acknowledgement of the addition of two new claims in the Response (see text on page 8 of the Response, which correctly indicates claims 1-19 as “previously pending in this application”), claims 22-23 are not considered as pending claims in the instant application. Pending claims remain claims 1-19.

3. On page 9 of the Response Applicant submits that “[t]he status of claim 7 is unclear to applicants”. Applicant’s attention is directed to section 2 of Paper No. 15. Specifically, because in communication of Paper No. No. 12, filed on February 13, 2003, the election of a single molecular embodiment of a fusion protein, such as GST as (aa) and huntingtin as (ab) polypeptides, was made. Claims, which correspond to the elected fusion protein are claims 1-6 and 8-11. Therefore, status of claim 7 is currently “withdrawn”, for not drawn to the elected subject matter.

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4. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

6. Applicant's arguments filed on December 31, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Sequence compliance

7. The instant specification remains not in compliance with Sequence Rules for reasons of record in section 4 of Paper No. 15. Applicant submits that "[t]he Substitute Sheets [...] added the appropriate Sequence identifiers to the specification". Applicant's attention is directed to the appropriate format for sequence identifiers, which is SEQ ID NO:X, wherein "X" is the sequence number. Appropriate correction is required.

Oath/Declaration

8. The oath or declaration in the instant application is defective for reasons of record in section 5 of Paper No. 15. Applicant is advised that oath submitted on December 31, 2003 appears to be an exact copy of the original defective oath. Specifically, it contains non-initialed and non-dated alterations that have been made to the second inventor's address.

A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

Drawings

9. In response to Applicant's request (page 12 of the Response), a copy of PTO948 form is resubmitted at this time.
10. Figures 10 and 11 submitted on December 31, 2003 are accepted by the Examiner.

Claim Rejections - 35 USC § 112

11. Claims 1-6, 8-11 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for those reasons of record specifically explained in section 8 of Paper No. 15.

Applicant traverses the rejection on the premises that the specification on pages 6-11 describes the preferred properties of the claimed genus of compounds and, further, that "[s]pecific examples of the members of those classes is set forth on page 8 and 11" (top at page 13 of the Response). These arguments have been fully considered but were not found to be persuasive for the following reasons.

Claims 1 and 5 are directed to a functional derivative of a fusion protein or huntingtin protein and claim 8 is directed to a functional fragment or derivative of GST. The Examiner maintains the position that the instant specification, as filed, fails to describe the entire genus of proteins which are encompassed by these claims. The claims encompass proteins, which are functional derivatives of a fusion protein comprising GST and huntingtin or functional fragments or derivatives of GST. Thus, the claims are not limited to a protein with a specific amino acid

sequence and only require the polypeptide to share some degree of structural similarity to the fusion protein comprising GST and huntingtin or to GST. Because the specification only describes one molecular embodiment, which is a fusion protein comprising GST and huntingtin or GST itself and fails to teach or describe any other molecular embodiments which lack the structure of a fusion protein comprising GST and huntingtin or GST itself and have the functions possessed by the recited protein and, further, because there is a lack of written description of relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure), one would reasonably conclude that the instant claims are directed to subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

12. Claims 5 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record in section 10 of Paper No. 15. Briefly, claim 5 is vague and indefinite in so far as it employs the term “huntingtin” as a limitation. Applicant submits that “[a]lthough the term “huntingtin” indeed does embrace a plurality of molecular species, the term is clear to one skilled in the art” (last paragraph at page 13 of the Response). This argument has been fully considered but is not deemed persuasive because by using this term without a reference to a precise amino acid sequence identified by a proper SEQ ID NO: or without identifying the property or combination of properties which is unique to and, therefore, definitive of a “huntingtin”, one skilled in the art clearly cannot determine if a compound which meets all

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of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

Claim Rejections - 35 USC § 102

13. The rejection of claims 1-6 and 8-11 under 35 U.S.C. 102(a) as being anticipated by Onodera et al. (FEBS Letters, 1996, 399, pp.135-9) is withdrawn in view of the new grounds of rejections in section 15 of the instant office action. In response to Applicant's statement "[I]t is unclear whether claim 5 is rejected in view of Onodera et al in view of the inconsistent numbering in the rejection" (top at page 15 of the Response), Applicant's attention is directed to the last paragraph of section 12 of Paper No. 15, which explains the reasoning of including claim 5 as being anticipated by the reference of Onodera et al..

Double Patenting

14. Double patenting warning regarding claims 1 and 6 stands for reasons of record in section 13 of Paper No. 15.

New grounds of rejection necessitated by amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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15. Claims 1-6 and 8-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amendment to claim 1 filed on December 31, 2003 introduced new matter into the claimed subject matter. Because Applicant failed to provide any information regarding the support of the instant amendment in the original disclosure, as filed, claim 1 and claims 2-6 and 8-11, which depend from claim 1, are rejected under 35 U.S.C. 112, first paragraph as containing new matter.

Conclusion

16. No claim is allowed.

17. This application contains claims 7 and 12-19 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

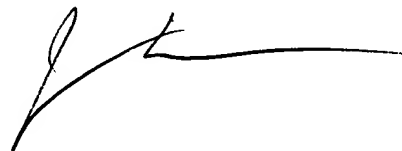
Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.



**JOHN ULM
PRIMARY EXAMINER
GROUP 1600**